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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,769	07/10/2003	Yu Momose	2630 US1P	3491

23115 7590 01/29/2007

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,769	MOMOSE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-13,15,18-24,29,30,32-38,43,45 and 47* is/are pending in the application.

4a) Of the above claim(s) *13,~~15~~,18-24,45 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-12,15,29,30,32-38 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 13, 18-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, Claims 45 and 47 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2006.

2. Applicant's election without traverse of invention group IH, directed to a method of treating or preventing Alzheimer's diseases, with the compound defined in claim 1, wherein the X is oxygen in the reply filed on November 13, 2006 is acknowledged.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 6-12, 15, 29-30, 32-38 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating senile dementia of Alzheimer's disease with the compounds wherein R1 is those defined in claim 6, A is those defined in claim 9, and B is those defined in claim 10, does not reasonably provide enablement for preventing senile dementia of Alzheimer disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re

Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. The court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claims are broadly cover method of treating and preventing senile dementia of Alzheimer's disease with compounds defined by the general formula in claim 1, which essentially encompasses unlimited number of compounds with various structurally distinct features. The specification discloses particular compound 1 and 5 have shown excellent NGF and BDNF production/secretion promoting activity. (experimental example 1). The specification nor the prior art of record provide any guidance for one of skill in the art to use the invention in expectation of administering a therapeutically effective amount of the oxazole derivatives herein for prevention senile dementia of Alzheimer. Particularly, the exact etiology of Alzheimer's diseases has not yet been fully understood (Pillay et al). The promotion of NGF and BDNF production/secretion while has been reasonably expected to interfere the development of Alzheimer's disease, but has not been shown to be effective for preventing Alzheimer's disease.

Further, the specification provide no working examples, or any rationale that compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is those defined in claim 6, A is those defined in claim 9, and B is those defined in claim 10, would be similarly effective as compounds 1 and 5, so that be useful for treating senile dementia of Alzheimer's disease. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The court in In re Fisher, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statue. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology of Alzheimer's disease. Further, various structural distinct compounds herein deemed to present unpredictability as to their physiological properties. For examples, R1 herein defined as halogen or any heterocyclic groups. The difference of the sizes, shapes and electronic distribution of the R1 would certainly affect the physical and chemical properties of the compounds and thereby affects the physiological property. In the instant case, the art and the evidence presented in the instant application fails to establish support for prevention senile dementia of Alzheimer's disease, or treatment of senile dementia of Alzheimer's disease with compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is those defined in claim 6, A is those defined in claim 9, and B is those defined in claim 10, as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 6-12, 15, 29-30, 32-38 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims recited method of treating or preventing senile dementia of Alzheimer *type.* The claims, or the specification provide no clear definition as to "Alzheimer's type". It is not clear what the other senile dementia is encompassed herein other than those of Alzheimer. The claims are indefinite as to the senile dementia encompassed thereby.

Double Patenting Rejections

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3, 6-12, 15, 29-30, 32-38 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-30 of U.S. Patent No.

6,605,629 in view of Mathew et al. (WO 99/16460). Claims 21-30 in '629 directed to a method for promoting neurotrophin production/secretion in a mammal in need thereof by administering the compounds herein. In light of the specification, the "mammal in need thereof" would apparently include senile dementia of Alzheimer's disease (page 39, line 33 to page 40, line 22). Further, it is well-known in the art, that high neurotrophin, such as NGF, is beneficial to neurodegenerative disease, such as Alzheimer's disease and dementia. See, e.g., pages 3 and 13 in Mathew et al. Therefore, it would have been obvious to one of ordinary skill in the art to practice the claimed invention of '629 by treating senile dementia of Alzheimer as Alzheimer patients are those "in need thereof" and it is well established in the art that neurotrophin, such as NGF, is beneficial for patient with Alzheimer's disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

SHENGJUN WANG
PRIMARY EXAMINER